



## General

### Guideline Title

Barrier methods for contraception and STI prevention.

### Bibliographic Source(s)

Clinical Effectiveness Unit. Barrier methods for contraception and STI prevention. London (UK): Faculty of Sexual and Reproductive Healthcare (FSRH); 2012 Aug. 28 p. [160 references]

### Guideline Status

This is the current release of the guideline.

This guideline updates previous versions:

Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. Female barrier methods. London (UK): Faculty of Family Planning and Reproductive Health Care; 2007 Jun. 17 p. [106 references]

Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. Male and female condoms. London (UK): Faculty of Family Planning and Reproductive Health Care; 2007 Jan. 17 p. [144 references]

## Recommendations

### Major Recommendations

The recommendation grades (A to C, Good Practice Point) are defined at the end of the "Major Recommendations" field.

#### How to Use Barrier Methods

##### Condoms (Male and/or Female)

Men and women requesting a barrier method should be informed of the efficacy of the method, including the failure rate relative to other methods such as long-acting reversible contraception. Information should be provided on correct use, factors affecting efficacy, and when sexually transmitted infection (STI) testing, emergency contraception (EC) and post-exposure prophylaxis after sexual exposure (PEPSE) to human immunodeficiency virus (HIV) may be required. (Good Practice Point)

##### Diaphragms and Caps

A diaphragm or cervical cap can be inserted with spermicide any time before intercourse. (Grade C)

Spermicide should be reapplied if sex is to take place and the diaphragm or cap has been in situ for  $\geq 3$  hours or if sex is repeated with the method in place. (Grade C)

A diaphragm or cervical cap should not be removed until at least 6 hours after the last episode of intercourse. (Grade C)

#### How Effective Are Barrier Methods at Preventing Pregnancy?

##### Condoms

Male condoms are 98% effective and female condoms are 95% effective at preventing pregnancy but only when used consistently and correctly. (Grade B)

Pregnancy rates are similar for latex and non-latex condoms. (Grade B)

##### Diaphragms and Caps

When used consistently, correctly and with spermicide, diaphragms and cervical caps are estimated to be between 92% and 96% effective at preventing pregnancy. (Grade C)

#### How Effective Are Barrier Methods at Preventing Transmission of STIs and Blood-borne Viruses?

##### Condoms

Sexually active men and women can be informed that the consistent and correct use of condoms (including with sex toys) is the most efficient means of protecting against HIV and other STIs. (Grades of evidence vary; see text in original guideline for specific infection/type of condom)

##### *HIV*

The consistent and correct use of male latex condoms is recommended to reduce the risk of HIV transmission. (Grade A)

The consistent and correct use of female condoms and non-latex male condoms may be recommended to reduce the risk of HIV transmission. (Grade C)

The use of male condoms can be advised for oral sex as a means of reducing the risk of HIV transmission. (Grade C)

Individuals living with HIV should be advised to use condoms to prevent onward transmission of HIV, superinfection with different HIV strains, and acquisition of other STIs. (Grade B)

##### *Chlamydia trachomatis*

The consistent and correct use of male or female condoms is recommended to reduce the risk of chlamydia transmission. (Grade B)

The use of male condoms can be advised for oral sex as a means of reducing the risk of chlamydia transmission. (Grade C)

##### *Neisseria gonorrhoeae*

The consistent and correct use of male and female condoms is recommended to reduce the risk of *N. gonorrhoeae* transmission. (Grade B)

The use of male condoms can be advised for oral sex as a means of reducing the risk of *N. gonorrhoeae* transmission. (Grade C)

##### *Trichomonas vaginalis*

The consistent and correct use of condoms is recommended to reduce the risk of *T. vaginalis* transmission. (Grade B)

##### *Syphilis*

The consistent and correct use of male condoms is recommended to reduce the risk of syphilis transmission. (Grade B)

The consistent and correct use of female condoms may be advised to reduce the risk of syphilis transmission. (Good Practice Point)

The use of male condoms can be advised for oral sex as a means of reducing the risk of syphilis transmission. (Grade C)

##### *Human Papillomavirus (HPV)*

The consistent and correct use of male (Grade B) and female condoms (Grade C) is recommended to reduce the risk of transmission of genital

HPV. (Grade B/C)

Male latex condoms, when used consistently and correctly, can increase the rate of HPV clearance and cervical intraepithelial neoplasia (CIN) regression. (Grade B)

The use of male condoms can be advised for oral sex as a means of reducing the risk of HPV transmission. (Grade C)

### *Herpes Simplex Infection*

The consistent and correct use of male condoms is recommended to reduce the risk of transmission of herpes simplex virus (HSV). (Grade C)

The consistent and correct use of female condoms may be advised to help reduce the risk of transmission of HSV. (Good Practice Point)

Individuals can be informed that whilst condoms offer some protection against HSV, avoidance of sex (vaginal, anal and oral) during symptomatic episodes may be advisable and that transmission can still occur by viral shedding even when there are no symptoms. (Grade C)

### *Viral Hepatitis*

The consistent and correct use of male condoms is recommended to reduce the risk of hepatitis B transmission. (Grade B)

The use of male condoms for oral sex may reduce the risk of hepatitis B transmission. (Grade C)

The consistent and correct use of male condoms is recommended to reduce the risk of hepatitis C transmission. (Good Practice Point)

There is insufficient evidence to determine the efficacy of condoms in preventing the risk hepatitis A during sexual activity. The use of dams is recommended for oral-anal contact. (Good Practice Point)

### *Diaphragms and Caps*

Women using a diaphragm or cervical cap should be aware that there is little evidence that these methods reduce the risk of HIV/STI transmission or development of CIN. (Grade C)

### *Dams*

Individuals should be informed that dams are available as a means of reducing risk of exposure to STIs and blood-borne viruses during cunnilingus and/or oro-anal contact. (Good Practice Point)

### Factors Affecting the Efficacy of Barrier Methods

#### *Spermicides*

Women using a diaphragm or cap should be advised to use the device with spermicide. (Grade C)

The use of condoms lubricated with nonoxinol-9 (N-9) is not recommended. (Grade B)

#### *Lubricants*

When using lubricant with latex condoms, diaphragms and caps a water- or silicone-based preparation is recommended. (Grade B)

The use of lubricant is recommended for anal sex to reduce the risk of condom breakage. (Grade B)

In terms of condom safety, there is insufficient evidence to routinely advise additional lubricant for vaginal sex, but its use can be considered for those experiencing condom breakage. (Grade C)

Men and women should be informed that adding lubricant to the inside of condoms or to the outside of the penis before using condoms is associated with an increased risk of slippage. (Grade B)

#### *Size, Shape and Thickness of Barrier Methods*

Ill-fitting condoms can be associated with breakage and incomplete use. Individuals should be informed that different shapes and sizes of condoms are available. (Grade C)

Condom breakage rates are similar for standard and thicker condoms and therefore there is no requirement to recommend thicker condoms for anal sex. (Grade C)

## Knowledge/Familiarity with the Method

Advice on condoms should be supported by demonstration of correct use. (Grade C)

## HIV/STI Transmission and the Law

Health professionals should keep up to date with the important legal issues regarding HIV/STI transmission and advise patients appropriately as regards partner notification, disclosure and condom use. (Good Practice Point)

## Considerations Following Barrier Method Failure

### Post-exposure Prophylaxis for HIV

Men and women can be made aware of PEPSE. The decision to initiate PEPSE can only be made after consideration of the risks of exposure and likelihood of side effects and compliance with treatment. (Good Practice Point)

### Pre-exposure Prophylaxis for HIV and Advance Provision of Emergency Contraception (EC)

Health professionals should utilise opportunities such as presentation for EC, PEPSE or STI testing to discuss pregnancy and STI risk reduction strategies. (Good Practice Point)

Health professionals should inform women about the availability of EC and when it can be used. Advance supply may be considered but there is no evidence to support routine provision. (Good Practice Point)

## Medical Eligibility

### HIV

For women living with HIV or at high risk of HIV infection the use of either a diaphragm or cervical cap is a UK Medical Eligibility Criteria for Contraceptive Use (UKMEC) Category 3. (Grade C)

### Sensitivity to Latex Proteins

Women with sensitivity to latex proteins should avoid the use of latex barrier contraceptives and may use a silicone diaphragm, cervical cap, non-latex male or female condoms, or deproteinised latex male condoms. (Grade C)

### Toxic Shock Syndrome (TSS)

For women with a history of TSS the use of the diaphragm, cervical cap or contraceptive sponge is a UKMEC Category 3. (Grade C)

Women with a history of TSS may use male or female condoms. (Grade C)

Caps and diaphragms should not be left in situ for longer than recommended by the manufacturer or used during menstruation. (Good Practice Point)

## Definitions:

### Grades of Recommendations

A: Evidence based on randomised controlled trials (RCTs)

B: Evidence based on other robust experimental or observational studies

C: Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities

Good Practice Point: Where no evidence exists but where best practice is based on the clinical experience of the multidisciplinary group

## Clinical Algorithm(s)

None provided

# Scope

## Disease/Condition(s)

- Unintended pregnancy
- Sexually transmitted infections (STIs), including human immunodeficiency virus (HIV) infection

## Guideline Category

Counseling

Evaluation

Prevention

## Clinical Specialty

Family Practice

Infectious Diseases

Internal Medicine

Obstetrics and Gynecology

Preventive Medicine

## Intended Users

Advanced Practice Nurses

Nurses

Patients

Physician Assistants

Physicians

Public Health Departments

## Guideline Objective(s)

- To provide evidence-based recommendations and good practice points for health professionals on the use of barrier methods to prevent pregnancy and/or reduce the risk of sexually transmitted infections (STIs), including the human immunodeficiency virus (HIV)
- To update two previous Faculty of Sexual & Reproductive Healthcare (FSRH) guidance documents on Male and Female Condoms and Female Barrier Methods published in 2007

Note: The term 'barrier method' is used in the document to refer predominantly to male and female condoms, diaphragms and the contraceptive cap.

## Target Population

Men and women seeking barrier methods to prevent pregnancy and/or reduce the risk of sexually transmitted infections (STIs)

## Interventions and Practices Considered

1. Counseling men and women concerning the consistent and correct use of barrier methods for contraception and sexually transmitted infection prevention, including:
  - Condoms (male latex, male and female non-latex)
  - Diaphragms and caps
  - Dams
2. Counseling men and women concerning factors affecting the efficacy of barrier methods, including:
  - Spermicides (e.g., nonoxynol-9)
  - Lubricants
  - Size, shape, and thickness of barrier methods
  - Knowledge/familiarity with the method
  - Duration of intercourse
3. Advising patients regarding legal requirements of partner notification, disclosure and condom use
4. Considerations following barrier method failure:
  - Emergency contraception
  - Testing for sexually transmitted infections
  - Post-exposure prophylaxis for human immunodeficiency virus (HIV)
  - Pre-exposure prophylaxis for HIV and advance provision of emergency contraception
5. Advising women living with HIV or at high risk of HIV infection that the use of either a diaphragm or cervical cap is not recommended
6. Advising women with sensitivity to latex proteins to avoid the use of latex barrier contraceptives and to use a silicone diaphragm, cervical cap, non-latex male or female condoms, or deproteinised latex male condoms
7. Advising women with a history of toxic shock syndrome on risks associated with diaphragms, caps, and sponges

## Major Outcomes Considered

- User acceptability and satisfaction
- Barrier failure rates (i.e., breakage/slippage)
- Rate of unintended pregnancy
- Rate of sexually transmitted infection, including human immunodeficiency virus (HIV)
- Rate of need for emergency contraception

## Methodology

### Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

### Description of Methods Used to Collect/Select the Evidence

Evidence is identified using a systematic literature review and electronic searches are performed for: MEDLINE (CD Ovid version) (1996–2012); EMBASE (1996–2012); PubMed (1996–2012); The Cochrane Library (to 2012) and the US National Guideline Clearing House. The searches are performed using relevant medical subject headings (MeSH), terms and text words. The Cochrane Library is searched for relevant systematic reviews, meta-analyses and controlled trials relevant to barrier contraceptive methods. Previously existing guidelines from the Faculty of Sexual & Reproductive Healthcare (FSRH) (formerly the Faculty of Family Planning and Reproductive Health Care), the Royal College of Obstetricians and Gynaecologists (RCOG), the World Health Organization (WHO) and the British Association for Sexual Health and HIV (BASHH), and reference lists of identified publications, are also searched.

## Number of Source Documents

Not stated

## Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Not Given)

## Rating Scheme for the Strength of the Evidence

Not stated

## Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

All papers are graded according to the Grades of Recommendations Assessment, Development and Evaluation (GRADE) system. Recommendations are graded using a scheme similar to that adopted by the Royal College of Obstetricians and Gynaecologists (RCOG) and other guideline development organisations. The clinical recommendations within this guidance are based on evidence whenever possible. Summary evidence tables are available on request from the Clinical Effectiveness Unit (CEU). The methods used in the development of this guidance have been accredited by National Health Service (NHS) Evidence.

## Methods Used to Formulate the Recommendations

Expert Consensus

## Description of Methods Used to Formulate the Recommendations

Clinical Effectiveness Unit (CEU) Guidance is developed in collaboration with the Clinical Effectiveness Committee (CEC) of the Faculty of Sexual & Reproductive Healthcare (FSRH). The CEU guidance development process employs standard methodology and makes use of systematic literature review and a multidisciplinary group of professionals. The multidisciplinary group is identified by the CEU for their expertise in the topic area and typically includes clinicians working in family planning, sexual and reproductive health care, general practice, other allied specialties, and user representation. In addition, the aim is to include a representative from the FSRH CEC, the FSRH Meetings Committee and FSRH Council in the multidisciplinary group (MDG).

## Rating Scheme for the Strength of the Recommendations

Grades of Recommendations

A: Evidence based on randomised controlled trials (RCTs)

B: Evidence based on other robust experimental or observational studies

C: Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities

Good Practice Point: Where no evidence exists but where best practice is based on the clinical experience of the multidisciplinary group

## Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

## Method of Guideline Validation

External Peer Review

Internal Peer Review

## Description of Method of Guideline Validation

Steps Involved in the Development of this Guidance Document

- Appointment of a multidisciplinary group (MDG) by invitation to main stakeholders.
- Revision of key questions by the Clinical Effectiveness Unit (CEU) and MDG.
- Systematic literature review, critical appraisal and development of evidence tables by the CEU researcher.
- Draft one guidance document is written by the CEU.
- Peer review by the MDG (written feedback and one-day meeting).
- Preparation of draft two guidance document by the MDG, the Faculty of Sexual & Reproductive Healthcare (FSRH), Clinical Effectiveness Committee (CEC) and two independent peer reviewers.
- Preparation of draft three guidance document based on written feedback.
- The MDG reviews the guidance and recommendations using a formal consensus process.
- Preparation of draft four guidance document.
- Draft four document is published on the Faculty website for up to 1 month for public consultation. Stakeholders are informed of this consultation process.
- All feedback comments are reviewed by the CEU, MDG, FSRH CEC and peer reviewers.
- The final draft is prepared and the CEU's response to consultation comments is posted on the FSRH website.
- The final document is published by the FSRH.
- Printed copies are mailed to FSRH members and an electronic version is made available on the FSRH website.
- Post-publication feedback is reviewed by the CEC and the web version is amended as and when necessary.

## Evidence Supporting the Recommendations

### Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

Appropriate use of barrier methods of contraception to decrease the rate of unwanted pregnancy and sexually transmitted infections

### Potential Harms

- Condom failure (e.g., break, slip, leak, put on too late and/or removed too early) may be a risk for pregnancy and/or infection.
- Diaphragm/cap failure (e.g., removed too early) may be a risk for pregnancy, and emergency contraception (EC) may need to be considered or used.
- Data from the USA have suggested that with perfect (i.e., correct and consistent) use there is a 5% failure rate with the female condom and

a 2% failure rate with the male condom. With typical use (which includes incorrect and inconsistent use) the failure rates are 21% and 18%, respectively.

- Incorrect condom use has been shown to be associated with an increased likelihood of condom breakage.
- The failure rates for cervical caps (but not diaphragms) may be increased for parous women.
- Women using a diaphragm or cervical cap should be aware that there is little evidence that these methods reduce the risk of human immunodeficiency virus/sexually transmitted infection (HIV/STI) transmission or development of cervical intraepithelial neoplasia.
- Men and women should be informed that adding lubricant to the inside of condoms or to the outside of the penis before using condoms is associated with an increased risk of slippage.
- Ill-fitting condoms can be associated with breakage and incomplete use.
- Repeated and high-dose use of nonoxynol-9 (N-9) is associated with an increased risk of genital lesions, which may in turn increase the risk of HIV acquisition.
- There is a small amount of evidence from case control studies to suggest that diaphragm and sponge use may be associated with an increased risk of non-menstrual toxic shock syndrome (TSS).

See Table 4: Summary of UK Medical Eligibility Criteria (UKMEC) categories in the original guideline document as they apply to different barrier methods.

## Contraindications

### Contraindications

- Diaphragms and caps are unsuitable for women who are less than 6 weeks postpartum.
- Diaphragms and caps should be avoided during menstruation.
- Women with sensitivity to latex proteins should avoid the use of latex barrier contraceptives.

## Qualifying Statements

### Qualifying Statements

- Recommendations are based on the evidence available at the time of writing and on consensus opinion of experts.
- The recommendations should be used to guide clinical practice but they are not intended to serve alone as a standard of medical care or to replace clinical judgment in the management of individual cases.
- For additional advice the Faculty of Sexual & Reproductive Healthcare Clinical Effectiveness Unit recommends that readers refer to the UK National Guidelines on Safer Sex Advice that were published by the British Association for Sexual Health and HIV (BASHH) as the guidance document went to press.

## Implementation of the Guideline

### Description of Implementation Strategy

An implementation strategy was not provided.

### Implementation Tools

Audit Criteria/Indicators

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents and Patient Resources* fields below.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

## IOM Care Need

Staying Healthy

## IOM Domain

Effectiveness

Patient-centeredness

## Identifying Information and Availability

### Bibliographic Source(s)

Clinical Effectiveness Unit. Barrier methods for contraception and STI prevention. London (UK): Faculty of Sexual and Reproductive Healthcare (FSRH); 2012 Aug. 28 p. [160 references]

### Adaptation

Not applicable: The guideline was not adapted from another source.

### Date Released

2007 Jun (revised 2012 Aug)

### Guideline Developer(s)

Faculty of Sexual and Reproductive Healthcare - Professional Association

### Source(s) of Funding

Faculty of Sexual and Reproductive Healthcare

### Guideline Committee

Clinical Effectiveness Unit

### Composition of Group That Authored the Guideline

*Guideline Development Group:* Dr Louise Melvin, Director, Clinical Effectiveness Unit; Ms Julie Craik, Researcher, Clinical Effectiveness Unit; Dr Soe Nyunt Aung, FSRH Clinical Standards Committee representative, Specialty Trainee in Community Sexual and Reproductive Health, Leeds Community Health Care NHS Trust; Dr Angela Ford, General Practitioner, Specialty Doctor, Sandyford, Glasgow; Mr Justin Gaffney, Genitourinary Nurse Association Chairman, Metrosexual Health, London; Mrs Lynn Hearton, FSRH Clinical Effectiveness Committee

representative, Helpline & Information Services Manager, Family Planning Association, London; Dr David Hicks, Divisional Medical Director, Barnsley Hospital NHS Foundation Trust, South Yorkshire; Ms Jane Morel, Area Manager, Terrence Higgins Trust Scotland, Glasgow; Mr Martin Murchie, President of the Society of Sexual Health Advisors, Sandyford, Glasgow; Dr Indhu Prabakhar, Subspecialty Registrar in Sexual and Reproductive Health, Liverpool; Dr Helen Ribbans, Consultant in Sexual and Reproductive Health, Burnley General Hospital, Burnley; Ms Clodagh Ross, Senior Nurse, Chalmers Sexual Health Service, NHS Lothian and Lecturer, School of Nursing, Midwifery & Social Care, Edinburgh Napier University

Administrative support to the Clinical Effectiveness Unit (CEU) team was provided by Ms Janice Paterson and Miss Jennifer Lyle.

## Financial Disclosures/Conflicts of Interest

Declared Interests: Dr Chris Mauck consults for CONRAD and the Population Council. Dr David Hicks has received payment for consultancy work for Reckitt Benckiser, producers of Durex® condoms.

## Guideline Status

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## Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the [Faculty of Sexual and Reproductive Healthcare Web site](#)

Print copies: Available from the Faculty of Sexual and Reproductive Healthcare, 27 Sussex Place, Regent's Park, London NW1 4RG

## Availability of Companion Documents

Discussion points and questions for barrier methods for contraception and sexually transmitted infection prevention developed by the Faculty of Sexual and Reproductive Healthcare are available at the end of the [original guideline document](#) .

In addition, auditable outcomes are available in the [original guideline document](#) .

## Patient Resources

None available

## NGC Status

This NGC summary was completed by ECRI Institute on May 16, 2008. This NGC summary was updated by ECRI Institute on October 1, 2012.

## Copyright Statement

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